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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,536	03/11/2004	Leah E. Appel	PC10270B	7842

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/799,536	APPEL ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/27/05 has been entered.

Terminal Disclaimer

The application/patent being disclaimed has been improperly identified since the number used to identify the application being disclaimed is incorrect. The correct number is 10/799,536. The terminal disclaimer filed 12/27/05 improperly identify the application number. It discloses the parent application number instead. Accordingly, the double patenting rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 49-68 and 70-77 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 15-45, 47-49 and 51-67 of U.S. Patent No. 6,706,283 ('283). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '283 patent claims a controlled release dosage form, comprising: (a) a core comprising an osmotic agent and a low solubility drug in the form of a solid dispersion of said drug in a dispersion polymer, at least a major portion of said drug being amorphous; (b) a water-permeable coating around said core having at least one delivery port therein, said coating controlling the influx of water to said core from an aqueous environment of use to cause extrusion of at least a portion of said core through said at least one delivery port to said aqueous environment of use, said coating being non-dissolving and non-eroding during release of said drug; wherein said osmotic agent comprises a water-swellable hydrophilic polymer that is separate from said dispersion polymer; wherein said dosage form provides an AUC in a use environment that is at least 1.25-fold that of a control dosage form comprising an identical dosage form containing an equivalent quantity of undispersed drug; and wherein said drug in said solid dispersion exhibits non-crystalline character in x-ray diffraction analysis. Cellulosic polymer including hydroxypropylmethyl cellulose acetate succinate (hpmcas) is found in claims 16, 30 and 48. The dosage form can be in the form of a bead (multiparticulate) is found in claims

17 and 52. The osmotic agent and the solid dispersion are in respective discrete portions, or in first or second layer is found in claims 19-21. Therefore, one of ordinary skill in the art would expect the same controlled release osmotic dosage form results from the use of the instant invention given the claims of '283. There are no unusual and/or unexpected results, which would rebut prima facie obvious. As such, the instant claims would have been obvious given the claims of '283, which set out a similar controlled release osmotic dosage form using the same ingredients, conditions, and techniques as claimed herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 49-58, 62-68, 70-74 and 76-78 are rejected under 35 U.S.C. 102(b) as being anticipated by Kerc et al. WO 96/36318.

Kerc discloses a pharmaceutical composition comprising a core, and a coating surrounding the core (page 4, 1st and 2nd paragraphs). The core comprises an amorphous drug dispersed in a polymer such as polyvinyl pyrrolidone and hydroxypropylmethyl cellulose with a viscosity from 3-1500 mPa.s (page 7; and example 1). The core is further mixed with excipients including cellulose ethers, glidant, filler, and lubricant (osmotic agent and

osmotically effective solute) (page 8, 2nd-3rd paragraph; page 9, 1st-2nd paragraph; and page 10, last paragraph through page 11, 2nd-3rd paragraph). The core is then coated with a film coating (page 9, paragraph 3 through page 10; page 11, paragraphs 2-3). Drug includes antibiotics, antihypertensives, antiparkinson, hypnotic, and those disclosed in page 5, 4th paragraph. The composition can be prepared in granule (multiparticulate) form, the granule can then be compressed into tablet, and the tablet is coated with a film (page 11; and examples).

It is noted that Kerc does not explicitly teach at least one delivery port. However, it is the position of the examiner that the exit port is an inherent feature, because Kerc teaches the use of the same drug (amorphous agent), the same osmotic agent (hydroxyethyl cellulose, hydroxypropyl cellulose, or hydroxypropylmethyl cellulose), the same osmotically effective solute (mannitol, sorbitol, glucose, or sodium chloride), the same dispersing polymer (hydroxypropylmethyl cellulose), and the same water-permeable coating. Accordingly, the water-permeable coating of the same polymer would have the same properties, *e.g.*, porous (delivery ports). Applicant's specification at page 23, lines 16-29, and page 24, lines 13-22, defines delivery ports as any opening or pores that are formed *in situ* during use. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, when the prior art

teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 49-58, 60-68, 70-74 and 76-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faour et al. US 6,004,582, in view of Kerc et al. WO 96/36318.

Faour teaches an osmotic device comprising a core comprises an active agent, an osmotic agent and polyvinyl pyrrolidone; a semi-permeable membrane; and a passage way (column 4, lines 63 through column 5, lines 1-30; and column 9, lines 52-58). Active agent is disclosed in columns 14-15. Semi-permeable membrane is made of material that remains its chemical and physical integrity in the environment of use (column 9, lines 1-16). The core further includes osmotically effective solutes (column 9, lines 38-51). Faour further teaches the use of tablet binder such as polyvinyl pyrrolidone, cellulose material, polypropylene glycol, and polyoxyethylene-polyoxyproprylene copolymer (column 10, lines 35-57).

Faour does not explicitly teach solid dispersion of a drug in its amorphous form. However, Kerc teaches dispersing an amorphous active agent in polymers is especially

suitable for active agents which exhibit poor solubility in crystal form (abstract). Thus, it would have been obvious to one of ordinary skill in the art to prepare the osmotic device of Faour using the solid dispersion of an amorphous drug in view of the teaching of Kerc, because Kerc teaches using amorphous active agent in which the solubility and the dissolution rate of the active agent will be independent of its polymorphous form, crystallinity, particle size and specific surface area, because Kerc teaches crystalline active agents have the essential disadvantage due to the presence of the crystalline in several polymorphous modification, crystal size, and results in a release rate that is not constant, because Faour teaches the use of poorly soluble drugs, and because Faour teaches the osmotic device can be prepared according to methods known in the art.

It is noted that the cited references do not teach the dosage form provides an AUC in a use environment that is at least 1.25 fold that of a control dosage form comprising an identical dosage form containing an equivalent quantity of undispersed drug, as claimed in claims 60 and 61. However, it is the position of the examiner that the osmotic device taught by Faour in view of Kerc would provide a similar AUC because references teaches the use of the claimed active agent, and the claimed dispersing polymer, as well as the claimed semi-permeable membrane.

Claims 49-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faour et al., in view of Kigoshi et al. US 6,254,889.

Faour is relied upon for the reasons disclosed above. Faour does not explicitly teach solid dispersion of a drug in its amorphous form, as well as the use of a specific dispersion polymer such as hydroxypropylmethyl cellulose acetate succinate.

Kigoshi teaches a solid dispersion dosage form of a slightly soluble drug comprising dispersing an amorphous drug in a dispersion polymer including hydroxypropylmethyl cellulose acetate succinate (see abstract; and column 3, lines 18-33). The dispersing solution is sprayed onto an absorbent carrier to obtain a drug core. The core is than mixed with excipient, and made into dosage form (column 4, lines 39-67). Thus, it would have been obvious to one of ordinary skill in the art to prepare the drug core of Faour using the solid dispersion of an amorphous drug in view of the teaching of Kigoshi, because Kigoshi teaches slightly soluble drugs have high crystallinity and low bioavailability, because Kigoshi teaches improving the solubility and bioavailability of slightly soluble drugs by dispersing slightly soluble drug in a polymer to form a solid dispersion, because Faour teaches the use of poorly soluble drugs, and because Faour teaches the osmotic device can be prepared according to methods known in the art.

It is noted that the cited references do not teach the dosage form provides an AUC in a use environment that is at least 1.25 fold that of a control dosage form comprising an identical dosage form containing an equivalent quantity of undispersed drug, as claimed in claims 60 and 61. However, it is the position of the examiner that the osmotic device taught by Faour in view of Kigoshi would provide a similar AUC

because references teaches the use of the claimed active agent, and the claimed dispersing polymer, as well as the claimed semi-permeable membrane.

Response to Arguments

Applicant's arguments filed 12/27/05 have been fully considered but they are not persuasive.

Applicant argues that Kerc does not disclose osmotic agents, nor does Kerc disclose that his dosage form should contain a delivery port of any type. Thus, withdrawal of the anticipation rejection over Kerc is respectfully requested. Contrary to the applicant's argument, it is noted that Kerc does discloses the claimed osmotic agent, see for example pages 8-9, including polyvinyl pyrrolidone, hydroxyethyl cellulose, hydroxypropyl cellulose, or hydroxypropylmethyl cellulose. Kerc also discloses the claimed osmotically effective solute, see for example page 9, 2nd paragraph, including starch, glucose, mannitol, sorbitol, or sodium chloride. Regarding the delivery port, as disclosed in the above 102(b) rejection, exit port is an inherent feature. It is inherently clear that the dosage form taught by Kerc would have at least one delivery port form *in situ*, because Kerc teaches the use of the same osmotic agent, the same osmotically effective solute, and the same water-permeable coating. Applicant's specification at page 23, lines 21-22, disclosed delivery port is formed *in situ* during use, whereby drug is delivered

through permeation through the coating. Accordingly, the 102(b) rejection by Kerc is maintained.

Applicant argues that Kigoshi simply discloses that some of the polymers useful as dispersion polymers in applicant's invention are known. Kigoshi does not otherwise fill in any of the shortcomings of the combination, and the examiner has not otherwise provided any basis as to how Kigoshi renders applicants' claims obvious. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Kigoshi teaches slightly soluble drugs have high crystallinity and therefore, low bioavailability. Thus, the solubility and bioavailability of slightly soluble drugs can be improved by dispersing slightly soluble drug in a polymer to form a solid dispersion.

Pertinent Arts

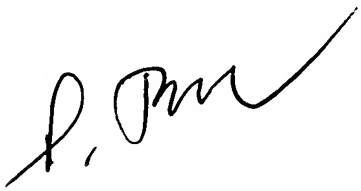
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gerber, Khanna et al., Curatolo et al., and Am et al. are cited as of interest for the teachings of solid dispersions.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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